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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,669	08/30/2000	Loren L Roy	17761-000950US	2031

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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 07/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/651,669	ROY ET AL.
Examiner	Art Unit	
Michael Peffley	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1)  Responsive to communication(s) filed on 28 May 2002.

2a)  This action is FINAL.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4)  Claim(s) 10-34 is/are pending in the application.  
4a) Of the above claim(s) 10-18 and 28-34 is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 19-27 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some \* c)  None of:

  1.  Certified copies of the priority documents have been received.
  2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.  
4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.

***Election/Restrictions***

Claims 10-18 and 28-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 5.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19, 20, 23, 24, 26 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards et al ('730).

Edwards et al disclose a balloon apparatus which includes a probe with a treatment surface for engaging target tissue, and a plurality of electrodes located on the surface (see Figure 3). The treatment surface is an expandable balloon, and the electrodes may be selectively activated (including activating peripherally located

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electrodes) and are operable in bipolar pairs. Edwards et al further disclose the delivery of a fluid through a conduit. While Edwards et al do not specifically disclose use of the device to shrink collagenous tissue, the examiner maintains that the device delivers energy sufficient to perform such a function. Applicant's recitation of this function is deemed to be a recitation of intended use which bears no patentable weight to the claims as this recitation fails to set forth any structure beyond what is disclosed by Edwards et al.

Claims 19-22 and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Underwood et al ('961).

Underwood et al disclose an electrosurgical device for the shrinking of collagenous tissue (Abstract). The device includes a thin, flat, rigid surface for contacting tissue, and a plurality of bipolar electrode pairs for delivering energy to tissue (Figure 21B). Underwood et al further disclose a conduit for the delivery of a fluid. Underwood et al disclose that the length of the treatment section may be between 2 and 20mm, and the width in a range from 2 to 10 mm (col. 29, lines 1-20). The electrodes are independently controlled such that peripheral electrodes may be energized independently.

Claims 19-22 and 24-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ingle et al ('238).

The Ingle et al system includes a surface for engaging tissue to shrink collagenous tissue by delivering energy to tissue through a plurality of bipolar electrode pairs (Figure 12). Ingle et al also disclose a conduit for providing a fluid to tissue (Abstract, Figure 1). The electrodes may be independently controlled, and the surface is within the size range set forth in the application claims.

***Claim Rejections - 35 USC § 103***

Claims 21 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al ('730) in view of the teaching of Ingle et al ('238) or Underwood et al ('961).

The Edwards et al device has been addressed previously. Edwards et al fail to disclose the use of a non-ablative energy level and the specific dimensions of the balloon. Ingle et al and Underwood et al both disclose the use of RF energy at non-ablative levels to shrink collagenous tissue. With regard to the dimensions of the balloon, the examiner maintains that one of ordinary skill in the art would recognize the acceptable range of dimensions which would be appropriate for the treatment of tissue, and that such an acceptable range would fall within the ranges set forth in applicant's claims.

To have provided the Edwards et al system with an RF supply which limited treatment to non-ablative levels for the shrinkage of collagenous tissues would have been an obvious consideration for one of ordinary skill in the art in view of the Underwood et al and/or Ingle et al teachings. To have further provided the Edwards et

al balloon with any reasonable size would have been an obvious design consideration for one of ordinary skill in the art.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19-27 are provisionally rejected under the judicially created doctrine of double patenting over claims 2-4 of copending Application No. 09/636,795. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: a probe having a treatment surface for the treatment of tissue to effect shrinkage of target tissue.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other

copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stern et al ('470), Bouchier et al ('993) and Swanson et al ('874) all disclose various surfaces containing multiple electrodes for contacting and treating tissue with providing a fluid to the tissue. Lax et al ('596) disclose a system for the RF treatment of collagen tissue to cause shrinkage of the treated tissue, and further teach the provision of a cooling fluid. Hall et al ('699) disclose an RF device with multiple electrodes located on a support surface.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (703) 308-4305. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

*Michael Peffley*  
Michael Peffley  
Primary Examiner  
Art Unit 3739

mp  
July 8, 2002